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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,354	10/06/2005	Keith M. Rosiello	350959-0004 THMX-001US	2403
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FOLEY & LARDNER LLP 111 HUNTINGTON AVENUE 26TH FLOOR BOSTON, MA 02199-7610			EXAMINER BOSWORTH, KAMI A	
			ART UNIT 3767	PAPER NUMBER
			MAIL DATE 11/24/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/552,354

**Applicant(s)**

ROSIELLO ET AL.

**Examiner**

KAMI A. BOSWORTH

**Art Unit**

3767

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 and 31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 and 31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 October 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. This office action is responsive to the amendment filed on 10/14/2008. As directed by the amendment: claims 1, 3, 10-15, 18, 21-25, and 31 have been amended. Thus, claims 1-26 and 31 are presently pending in this application.

### ***Response to Arguments***

2. Applicant's arguments with respect to claims 1-26 and 31 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-4, 9, 11-15, 17-19, and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Shigezawa (US Pat 6,641,556).

5. Re claim 1, Shigezawa discloses a system (as seen in Fig 1) for heating a fluid for delivery into a body of a patient comprising: a fluid delivery-line (as seen in Fig 1) comprising: a tube 120 (Fig 1, 3) for communicating a fluid; two thermal sensors 130,

138 (Fig 3), at least one thermal sensor positioned proximate to each end of the tube (as seen in Fig 3); and a heating element 146 (Fig 3, 4) positioned proximate a surface of the tube (as seen in Fig 4) to heat fluid within the tube, the heating element being controlled based on temperature data from the two or more thermal sensors to generate a determined heat gradient through the fluid within the tube (Col 4, Lines 44-65).

6. Re claim 2, Shigezawa discloses a controller 116 (Fig 1).
7. Re claim 3, Shigezawa discloses that the heating element is spaced apart from an outer surface of the tube (as seen in Fig 4).
8. Re claim 4, Shigezawa discloses that a wall 132 (Fig 4) of the tube comprises a thermal medium for distributing heat received by the outer surface of the tube from the heating element (Col 4, Lines 27-29).
9. Re claim 9, Shigezawa discloses that the heating element is surrounded by a thermal medium 132 (Fig 4; Col 4, Lines 27-29).
10. Re claim 11, Shigezawa discloses that the fluid delivery-line includes a bag spike positioned at one end (as seen in Fig 1).
11. Re claim 12, Shigezawa discloses that the fluid delivery-line includes a transfusion needle 122 (Fig 1) and a luer lock 140 (Fig 3) at one end.
12. Re claim 13, Shigezawa discloses that the heating element and the two or more thermal sensors are in electrical contact with the controller (via electrical leads 134, 150 in conduit 136; Fig 3).
13. Re claim 14, Shigezawa discloses that the controller is connected to a power source (Col 3, Lines 21-23).

14. Re claim 15, Shigezawa discloses that the power source is AC power (Col 3, Lines 21-23).
15. Re claim 17, Shigezawa discloses that the controller provides an electrical current to the heating element (Col 4, Lines 27-34 and 44-65).
16. Re claim 18, Shigezawa discloses that the controller controls the temperature of the tube by sensing a temperature corresponding to a temperature of fluid within the tube and adjusting the amount of current supplied to the heating element (Col 4, Lines 44-65).
17. Re claim 19, Shigezawa discloses a heat element connector 134 (Fig 3) and thermal sensor connector 134 (Fig 3) for connecting the heat element and thermal sensor, respectively, to corresponding connectors on the controller.
18. Re claim 23, Shigezawa discloses a heat-conductive member 132 (Fig 4) having a first portion placed adjacent an interior portion of the tube (as seen in Fig 4) and a second portion placed proximate the heating element (as seen in Fig 4), wherein the heat-conductive material transfers heat from the heating element to the interior portion of the tube (Col 4, Lines 27-29).

***Claim Rejections - 35 USC § 103***

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. Claims 5-8, 22, 24, 25, 26, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shigezawa in view of Swenson (US Pat 5,195,976).

21. Re claims 5 and 6, Shigezawa discloses all the claimed features except that the heating element spirally surrounds the tube. Swenson, however, teaches a Heating element 43 (Fig 2) that surrounds a tube 32 (Fig 2) for the purpose of heating an IV fluid (Col 11, Lines 49-51). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Shigezawa to include a heating element that spirally surrounds the tube, as taught by Swenson, for the purpose of heating an IV fluid (Col 11, Lines 49-51).

22. Re claim 7 and 8, Shigezawa discloses all the claimed features except that the heating element comprises a plurality of heating elements circumferentially surrounding the tube and spaced apart from each other along a length substantially parallel to a length of the tube. Swenson, however, teaches a plurality of heating elements 48 (Fig 3, 4) that circumferentially surround the tube (as seen in Fig 4), spaced apart from one another along a length substantially parallel to a length of tube 32 (Fig 3) for the purpose of heating an IV fluid (Col 6, Lines 42-48). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Shigezawa to include a plurality of heating elements circumferentially surrounding the tube, as taught by Swenson, for the purpose of heating an IV fluid (Col 6, Lines 42-48).

23. Re claim 22, Shigezawa discloses all the claimed features except a metering means for determining a flow rate of fluid traversing through the tube. Swenson, however, teaches a metering means 22 (Fig 1B) for determining a flow rate of fluid

traversing through a tube 32 (Fig 1B) for the purpose of providing precise fluid temperature information (Col 7, Lines 16-18). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Shigezawa to include metering means for determining a flow rate, as taught by Swenson, for the purpose of providing precise fluid temperature information (Col 7, Lines 16-18).

24. Re claims 24 and 25, Shigezawa discloses a thermal medium 132 (Fig 4) but does not disclose that the thermal medium is positioned between the tube and an insulative tube. Swenson, however, teaches a thermal medium 46 (Fig 3) positioned between a tube 32 (Fig 3) and an insulative tube 47 (Fig 3) for the purpose of keeping the IV fluid warm (Col 8, Lines 19-22). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Shigezawa to include a thermal medium positioned between the delivery tube and an insulative tube, as taught by Swenson, for the purpose of keeping the IV fluid warm (Col 8, Lines 19-22).

25. Re claim 26, Shigezawa discloses that the thermal medium 132 (Fig 4) envelops the heating element 146 (Fig 4).

26. Re claim 31, Shigezawa discloses a system (as seen in Fig 1) for heating a fluid for delivery into a body of a patient comprising: a controller 116 (Fig 1); and a fluid delivery line (as seen in Fig 1) having a first end 114 (Fig 3) for receiving fluid from a fluid source 102 (Fig 1) and delivering the fluid to a destination, the fluid delivery line comprising: a fluid delivery tube 120 (Fig 1, 3) for communicating a fluid; two thermal sensors 130, 138 (Fig 3), at least one thermal sensor positioned proximate the fluid delivery tube (as seen in Fig 3); a heating element 146 (Fig 3, 4) positioned proximate

the fluid delivery tube (as seen in Fig 4), the heating element being controlled based on temperature data from the two or more thermal sensors to generate a determined heat gradient through the fluid within the tube (Col 4, Lines 44-65); and a thermal medium 132 (Fig 4). Shigezawa does not disclose that the thermal medium is positioned between the fluid delivery tube and an insulative tube. Swenson, however, teaches a thermal medium 46 (Fig 3) positioned between a tube 32 (Fig 3) and an insulative tube 47 (Fig 3) for the purpose of keeping the IV fluid warm (Col 8, Lines 19-22). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Shigezawa to include a thermal medium positioned between the delivery tube and an insulative tube, as taught by Swenson, for the purpose of keeping the IV fluid warm (Col 8, Lines 19-22).

27. Claims 10 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shigezawa in view of Lenker (US Pat 6,746,439).

28. Re claim 10, Shigezawa discloses a thermal medium but does not disclose that the thermal medium comprises a fluid. Lenker, however, teaches a delivery tube 146 (Fig 4) which has a thermal medium that comprises a fluid 158 (Col 7, Lines 9-12) for the purpose of transferring heat to the IV fluid (Col 7, Lines 37-40). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Shigezawa to include a thermal medium that comprises a fluid, as taught by Lenker, for the purpose of transferring heat to the IV fluid (Col 7, Lines 37-40).

29. Re claim 16, Shigezawa discloses all the claimed features except that the tube is sterile prior to use. Lenker, however, teaches that tube 146 (Fig 4) is sterile prior to use



(Col 8, Lines 54-55) for the purpose of ensuring sterile contact between the device and a patient (Col 8, Lines 56-59). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Shigezawa to include a tube that is sterile prior to use, as taught by Lenker, for the purpose of ensuring sterile contact between the device and a patient (Col 8, Lines 54-59).

30. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shigezawa in view of Cassidy et al. (US Pat 6,175,688).

31. Re claims 20 and 21, Shigezawa discloses all the claimed features except a temperature actuated valve that opens upon the temperature of a fluid within the tube reaching a predetermined value. Cassidy et al., however, teaches a substantially similar device having a temperature actuated valve 702 (Fig 13) that opens upon the temperature of the fluid within the tube reaching a predetermined value (Col 13, Lines 1-36) for the purpose of protecting a patient from inadequate flow conditions in the line (Col 13, Lines 33-36). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Shigezawa to include a temperature actuated valve, as taught by Cassidy et al., for the purpose of protecting a patient from inadequate flow conditions in the line (Col 13, Lines 33-36).

### ***Conclusion***

32. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAMI A. BOSWORTH whose telephone number is (571)270-5414. The examiner can normally be reached on Monday - Thursday, 7:00 am to 4:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K. A. B./  
Examiner, Art Unit 3767  
/Kevin C. Sirmons/  
Supervisory Patent Examiner, Art Unit 3767